ZEVEX
INCORPORATED

K954735

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SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

This summary was prepared on October 6, 1995.

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Name of device: *EnteraLite*™ Enteral Feeding Pump

Common name: Enteral Infusion Pump

Classification name: Infusion Pump, Enteral, External (80LZH) as defined in 21 CFR 880.5725.

Predicate device: The predicate device is the Kangaroo® PET® Enteral Feeding Pump and Charger Base manufactured by:

Sherwood Medical
1915 Olive Street
St. Louis, MO 63105-1642
(314) 621-7788
FDA Registration Number 1924954

ZEVEX, Incorporated believes the EnteraLite enteral feeding pump is substantially equivalent to the Kangaroo PET device reviewed by FDA under Document Control number K913413 and its introduction into interstate commerce raises no new questions of safety or efficacy.

The predicate device for the disposable feeding set is the disposable set used with the Kangaroo® PET® Enteral Feeding Pump manufactured also by Sherwood Medical. ZEVEX, Incorporated believes the EnteraLite disposable feeding set is substantially equivalent to the Kangaroo PET disposable feeding set reviewed by FDA under document control number K851539 and its introduction into interstate commerce raises no new questions of safety or efficacy.

INFUSION PUMP DESCRIPTION

The EnteraLite enteral feeding pump with disposable set is a small, lightweight pump used to dispense liquid nutrients at a user controlled rate to patients. The device may be used in the hospital or at home by bed-ridden or ambulatory patients. The device is also designed for use with pediatric patients.

The device is a software controlled, variable flow rate, peristaltic pump. It operates up to 24 hours (at a nominal flow rate of 125 ml/hr) from internal rechargeable batteries. The batteries are recharged by a wall mounted charger that plugs into a standard 120 volt alternating current wall socket. The charger is available in various input voltage and plug configurations to accommodate international requirements. The charger converts line voltage to a safe low voltage of 12 volts DC that is supplied from the charger to the pump. A "fuel gauge" type indicator on the pump's LCD display continuously shows the state of battery charge.

The pump motor runs at a single speed and is turned on and off at programmed intervals to obtain the desired flow rate. The motor drive circuit is controlled by a microcontroller that allows the motor to pause longer at lower flow rates with correspondingly shorter pauses at higher flow rates. The software embodied within the microcontroller was extensively validated and verified as part of the design process.

The pump includes several safety features. An air-in-line sensor rapidly detects whenever nutrient flow is interrupted and alerts the user with both a visual and audible alarm. Two pressure sensors detect occlusions both on the nutrient bag (distal) side and the patient (proximal) side of the pump. The user is alerted to proximal or distal occlusions by both visual and audible alarms.

A backpack (convertible to a fannypack) is available for use under ambulatory conditions. The pump may be operated in any orientation.

DISPOSABLE TUBING SET DESCRIPTION

The ZEVEX disposable nutrient administration set is comprised of nine components. All components of the set remain extracorporeal. The ZEVEX set interfaces with the *in vivo* apparatus via an industry standard non-I.V. compatible stepped adapter. The disposable set includes a short length of silicone tubing that is stretched around the three feeding pump rollers. As the rollers turn, they occlude the tubing forcing the nutrient solution through the silicone pump tube. The set also includes a unique fail safe device that precludes free-flow when the set is not correctly installed in the pump with the door closed. Pull tests were done to assure that the set would not be easy to inadvertently disconnect when in use.

STERILIZATION PARAMETERS

Neither the pump nor the disposable set is supplied in a sterile condition.

SUBSTANTIAL EQUIVALENCE COMPARISON

Feature	EnteraLite™	Kangaroo® PET™
Hospital, Ambulatory, & Home Use	Yes	Yes
Pediatric Use	Yes	Yes
Pumping Mechanism	Rotary Peristaltic	Rotary Peristaltic
Operating Orientation	Any	Upright Only
Flow Monitoring	Yes	Yes
Size (w/o charger)	4.97"H x 4.47"W x 2.00"D (12.6 x 11.3 x 5.1 cm)	5.75"H x 3.81"W x 2.00"D (14.4 X 5.1 X 9.7 cm)
Weight w/ charger	576 grams (1.27 pounds) 1,093 gms (2.41 pounds)	635 grams (1.41 pounds) 1,578 gms (3.48 pounds)
Charger	Yes - Wall mount	Yes - Charger Base
Drip-proof	Yes	Yes
Dose-limit (ml)	10 to 3000 x 10ml increments	1 to 75ml in 1ml increments 75 to 2000ml in 5ml inc.
Flow-rate (ml/hour)	1 to 600 in 1ml increments	1 to 75 in 1ml increments 75 to 400 in 5ml increments
Flow Accuracy	± 5% including high viscosity solutions	± 10%
Fast prime	30 sec fast prime @ 600 ml/hr	No prime feature
Battery Type	Nickel Metal Hydride	Nickel Cadmium
Time between charges	24 hours	16 hours
Charger Type	External wall mounted	External base
Charge time (from full discharge)	Five hours	Eight hours
Display	LCD (green electroluminescent)	LED (red)
Certification	Designed to meet UL and TÜV requirements	UL-544
Occlusion Pressure	Select 8psi or 12psi (± 2psi)	15 psi
Air-in-line Sensor	Yes	No
Continuous Indication of Battery Charge Level	Yes	No
Improper Loading Indication	Yes	Yes
Charger Power Requirements	105 to 129 VAC, 60 HZ, 0.5 Amp	120V ±15%, 50/60 Hz, 0.1 Amp
Pole Clamp Mountable	Yes	Yes
Supplied Sterile	No	No
Backpack	Yes - Convertible to fanny pack	Yes - Upright only
510k clearance	This submission	K913413

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ALARM COMPARISON

ALARM	EnteraLite	Kangaroo PET
DOSE DONE	YES	YES
NO FOOD/EMPTY SET	YES	YES
LOAD SET	YES	YES
UPSTREAM OCCLUSION	YES	YES
DOWNSTREAM OCCLUSION	YES	YES
LOW BATTERY	YES	YES
INTERVAL PROGRAM ERROR	YES	NO
MOTOR OBSTRUCTION	YES	YES
TIME OUT (HOLD ERROR)	YES	YES
SELF DIAGNOSTICS	YES	YES

TUBING SET COMPARISON

Feature	ZEVEX Disposable Set	Kangaroo Disposable Set
Automatic Anti-free Flow	Yes	No
Drip Chamber	No	Yes
1,200 ml Bag	Yes	Yes
500 ml Bag	Yes	Yes
Spike Set	Yes	Yes
Silicone Pump Segment	Yes	Yes
PVC Tubing	Yes	Yes
Non-toxic	Yes	Yes
In contact with patient's body	No	No
510(k)	This submission	K851539

REFERENCES

(1) **Guidance on the Content of Premarket Notifications [510(k)] Submissions for External Infusion Pumps,** FDA CDRH/ODE, March 1993.

(2) **Infusion Pump State Contract Investigation: Summary Report,** HHS Publication FDA 93-4256.

(3) **Medical Device Tracking Requirements,** Chapter 21, Code of Federal Regulations, Part 821.

(4) **Infusion Devices,** American National Standard ANSI/AAMI ID26-1992.

(5) Recommendations for Developing User Instructions for Medical Devices Used in Home Health Care, **Write It Right,** HHS Publication FDA 93-4258, August, 1993.

(6) **FDA Public Health Advisory,** Infusion Pumps, March 1, 1994.

(7) **Medical Electrical Equipment, Part 1: General Requirements for Safety,** UL2601-1 Revised December 2, 1994.

(8) **Reviewer Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review,** FDA CDRH/ODE Document, 29 August, 1991.

(9) **Infusion Pump**, 21 CFR §880.5725, 80LZH, Class II

(10) **Gastrointestinal Tube and Accessories**, 21 CFR §876.5980, 78KNT, Class II